

REMARKS

Claims 45-48 have been amended to generalize the required function of the claimed composition to eliciting an “immunological response” in general rather than necessarily to prostate cancer per se. This amendment is made in accordance with the discussion at the interview as it is believed to obviate certain issues that may exist regarding predictability of anti-cancer vaccines. It is clear that the compositions claimed which contain the STEAP-2 protein identified by amino acid sequence and by deposit number will be able to elicit an immunological response. This immune response is useful either, as applicants contend, to mitigate the progression of a cancer which expresses this protein, or to provide antibodies which are useful for detecting the STEAP-2 protein and for identifying prostate tissue generally. No new matter has been added and entry of the amendment is respectfully requested.

Formal Matters

As to the issue regarding the deposit, applicants hereby state that the deposit comprising ATCC accession no. PTA-311 was made under the terms of the Budapest Treaty and that all restrictions on access to this deposit will be removed upon issuance of a U.S. patent based on this application.

With respect to the objection to the portion of the sequence listing which is submitted as replacement tables for page 49, applicants respectfully request reconsideration. The Office asserts that all sequence disclosures whether they are portions or fragments of pre-disclosed sequences are considered unique sequence and require separate identifiers - i.e., SEQ. ID NOs. However, this does not appear to be the case. MPEP 2422.04 states on page 2400-35 “sequence identifier can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as ‘residues 14-243 of SEQ. ID NO. 23’ is permissible and the fragment need not be separately presented in the ‘sequence listing.’”

Thus, the presented amendment on page 7 of the previous response suggesting two tables for page 49 complies with this requirement. The sequence itself is given and the start position of

that sequence is provided in column 2 of the table. Thus, the end position is readily obtainable from the sequence itself - e.g., GLLSFFFAV would represent positions 165-173 of SEQ. ID NO. 2.

Withdrawal of this objection is thus respectfully requested.

The Rejections Under 35 U.S.C. § 112, First Paragraph

This rejection is retained for two reasons which are addressed separately. First, the Office maintains its position that eliciting an immunological response to prostate cancer is unpredictable under any circumstances. While applicants do not agree with this assessment as applied to its impact on patentability of the claimed subject matter, amendment has been made to the claims to clarify that a simple immunological response is all that is required. There is really no doubt that administering a protein of this size would elicit an immunological response. As stated above, eliciting such a response is useful in a number of contexts, including the production of antibodies which would permit the identification of prostate tissue. Accordingly, this aspect of the rejection is believed obviated.

The second aspect is based on doubt that the evidence set forth in the specification is sufficient to demonstrate that the STEAP-2 protein actually exist in the prostate or prostate tumor tissue. This aspect of the rejection is not unrelated to the first, since one requirement for eliciting an immunological response to prostate tissue or a cancer would be the presence of this protein.

As agreed at the interview, enclosed herewith is declaratory evidence of Mary Faris, Ph.D. that the STEAP-2 protein is actually translated from the mRNA. First, Dr. Faris notes in paragraph 3 that evidence of Northern blotting is recognized as a reliable index of production of the protein encoded by the mRNA detected. But in the present case, there is additional specific evidence of this fact. The Declaration describes experiments which demonstrate that the STEAP-2 protein must have been produced in cells because metabolic effects were exerted by the introduction of an expression system for this protein. The nature of these results is summarized in paragraph 4 of the Declaration. Not only is it demonstrated that an expression

system for STEAP-2 produced metabolic results that can only be exhibited at the protein level, modifying the STEAP-2 protein to alter its conformation by attaching a Flag epitope diminished these effects. These experiments are explained in detail in the Declaration and show conclusively that mRNA encoding STEAP-2 is indeed translated into protein. Accordingly, this aspect of the rejection may also be withdrawn properly.

Conclusion

Applicants again express their appreciation to Examiners Nickol and Caputa for their helpful discussion at the interview. The amendment to the claims clarifies the general nature of the immunological response to be elicited by the claimed STEAP-2 protein. The Declaration of Dr. Faris establishes that STEAP-2 protein is indeed produced from mRNA. Accordingly, the bases for rejection under 35 U.S.C. § 112, first paragraph, are believed overcome and passage of claims 1 and 44-48 to issue is respectfully requested.

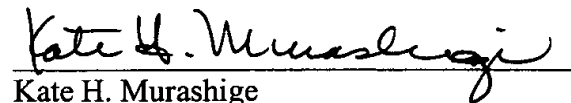
If outstanding issues remain which the Examiner believes can be resolved by a telephone discussion, a telephone call to the undersigned is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 511582001620.

Respectfully submitted,

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By:



Kate H. Murashige
Registration No. 29,959

Morrison & Foerster LLP
3811 Valley Centre Drive,
Suite 500
San Diego, California 92130-2332
Telephone: (858) 720-5112
Facsimile: (858) 720-5125

EXHIBIT A. - VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please amend as follows:

45. (Amended) A composition for inducing an immunological response[to prostate cancer], which cancer expresses a STEAP-2 protein, said composition comprising a STEAP-2 protein according to claim 1 and a physiologically acceptable carrier.

46. (Amended) A kit for inducing an immunological response[to prostate cancer], which kit comprises a carrier compartmentalized to receive, in close confinement, one or more containers, wherein one of said containers comprises the composition of claim 45.

47. (Amended) A composition for inducing an immunological response[to prostate cancer], which cancer expresses a STEAP-2 protein, said composition comprising a STEAP-2 protein according to claim 44 and a physiologically acceptable carrier.

48. (Amended) A kit for inducing an immunological response[to prostate cancer], which kit comprises a carrier compartmentalized to receive, in close confinement, one or more containers, wherein one of said containers comprises the composition of claim 47.